

Appl. No. 10/039,753  
Amdt. dated: December 7, 2006  
Response to Final Office Action of November 22, 2006

#### REMARKS

Claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-39 are pending in this application. According to the Office Action Summary, claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-39 are rejected, claim 34 is allowed, and claim 35 is objected to. However, after reading the specific rejections in the Office Action, applicant believes that there may be an error in line 6 of the Office Action Summary as it is inconsistent with line 5 of the Office Action Summary, and since there are no objections to or rejections of claim 34,

By the present amendment, the specification is amended to provide the correct filing date of the second-filed provisional application, namely Application 60/283,432, to which the present application properly claims benefit. (See the filing receipts for (a) the present application, (b) US Provisional Application 60/259,340 (hereinafter "Provisional '340"), and (c) US Provisional Application 60/283,432 (hereinafter "Provisional '432"), copies of which are all attached hereto for the Examiner's convenience. See also 37 CFR 1.78, a copy of which appears on page 1 of the document marked "Appendix", which is attached hereto for the Examiner's convenience, and which states that a non-provisional application can claim benefit to more than one provisional application.) Paragraph 1 has also been amended to use the language suggested in MPEP 201.11 (B) for claiming benefit of the filing date of a provisional application. (See MPEP 201.11, which also appears on page 1 of the attached Appendix.) By the present amendment, claims 1, 2, 23, 26, 28, 29, 31, 32, 33, 35, 36, 37, and 38 are amended for clarity. The amendments are fully supported by the application and add no new matter.

Applicant thanks the Examiner for the telephone conference of December 1, 2006, during which the §102/103 rejection based on the absence in Provisional '432 of a priority claim to or more specifically "an incorporation by reference" of Provisional '340 (see Page 5 of the Office Action) was discussed, and the telephone conference of December 4, 2006, during which the meaning of the term "risk of having" was discussed.

In view of the above-described amendments and following remarks, reconsideration of claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-33 and 35-39 is respectfully requested.

#### Objections

Claims 2, 28, 32, 35, and 38 are objected to under 37 CFR 1.75(c) as being of improper

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dependent form. The base claims for claim 2, namely claim 1, and the base claim for claim 35, namely claim 34, recite that the blood leukocytes are "selected from the group consisting of neutrophils and monocytes, or any combination thereof". The base claim for claims 28 and 32, namely claim 23, and the base claim for claim 38, namely claim 37, recite that the blood leukocytes are selected "from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereof". To ensure that the rejected claims are not of broader scope than their base claims, claims 2, 28, 32, 35, and 38 have been amended to no longer recite "one or more populations of leukocytes". In addition, the rejected claims have also been amended for clarity to recite that it is "said blood leukocytes", i.e., the blood leukocytes recited in the base claim, that are being tested in the assay. Applicants submit that the amendments overcome the objections. If the Examiner disagrees, Applicants request that he call Pamela A. Docherty at (216) 622-8416 to discuss further amendments.

#### § 112 Rejections

Claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-33. and 35-39 are rejected under 35 USC § 112, second paragraph "as being indefinite."

With respect to the term "risk of having" that appears in independent claims 1, 23, 31, and 33 of the present application, this term means that a subject with high levels of MPO has a high probability of having atherosclerotic cardiovascular disease (CVD). Thus, the methods recited in claims 1, 23, 31, and 33, and the claims that depend therefrom, are prognostic methods as opposed to the "gold-standard" diagnostic test for atherosclerotic CVD, i.e., angiography.

Claims 23 and 37 have been amended to remove the second inclusion of "sub-populations of neutrophils. Claims 23 and 26 have been amended for clarity to identify the bodily samples that are used to determine levels of MPO and to ensure that the bodily sample of the "determining" clause and the bodily sample of the "wherein" clause are consistent and of the same scope.. Applicants submit that the amendments to claims 23, 26, and 37 overcome the §112 rejection. If the Examiner disagrees, Applicants request that he call Pamela A. Docherty, at (216) 622-8416 to discuss further amendments.

#### §102/103 Rejections

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Claims 23, 26, 29, 37, and 39 are rejected under 35 USC §102(a) as anticipated by or alternatively under 35 U.S.C. 103(a) as being obvious over Zhang et al (JAMA, 286, 2136) (hereinafter Zhang et al). As stated in the Office Action:

The reference has a 102(a) date because the instant claims are only accorded benefit of the instant filing date of 1/3/02.....Claims are deemed broader because of at least the following features:

- 1) the nature of the controls. ....There is no teaching of controls from the "general population" and there is no teaching of any "select population of controls" other than "healthy" controls." In amended claim 26, the nature of the "control subjects" has not been changed so that they are of the same scope as the "healthy controls of Prov. Applic 60/283,432.
- 2) the nature of the sample. In the '432 application the "leucocytes are limited to neutrophils or sub-populations of monocytes or any "combinations that would include these. In amended claim 23, and in new claim 37, applicant has included these sub-populations. Applicant has urged that earlier filed US Prov. Applic. 60/259,340 teaches such sub-populations at p. 9. While the examiner concurs that this teaching is present, it is not effective, because later filed Prov. Applic. 60/283,432 did not incorporate Prov. Applic. 60/259,340 by reference. Applicant wants to rely upon the disclosure of Prov. Applic. 60/259,340 in order to obtain an effective filing date of 1/2/01 for overcoming the Zhang et al reference; it is to be noted, however, that this reference fails to disclose blood, serum, or plasma examples. Thus, Prov. Applic 60/259,340 would fail to support instant claims encompassing the use of blood serum or plasma samples. (See pages 4 and 5 of the Office Action.)

The present application properly claims benefit to two provisional applications, namely US Provisional Application 60/259,340 filed Jan. 2, 2001 (hereinafter "Provisional '340") and U.S. Provisional Application 60/283,432, filed April 12, 2001 (hereinafter "Provisional '432"). Thus, with respect to the embodiments disclosed in Provisional '340 and Provisional '432, the present application has two effective filing dates, both of which antedate Zhang et al.

According to 37 CFR 1.78, which is shown on page 1 of the attached Appendix, a later-filed non-provisional application can claim the benefit of multiple prior-filed provisional applications as long as each prior-filed provisional application names "as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112". (See 37 CFR 1.78) As noted in the filing receipts that are attached hereto, the present application and Provisional applications '340 and '432 all name Stanley Hazen and

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Renliang Zhang as inventors. Moreover, Provisional applications '340 and '432 both disclose methods of characterizing a test subject's risk of developing or having atherosclerotic vascular disease by determining levels of MPO mass in blood samples. (See Page 3 of Provisional '340 and Provisional '432.) In addition, Provisional '340 and Provisional '432 both recite subpopulations of neutrophils and monocytes. (See page 9, line 4 of Provisional '340 and page 9, line 8 of 'Provisional '432.) Finally, the present nonprovisional application was filed within 12 months from the filing date of Provisional '340 and Provisional '432. (See the attached filing receipts.) Thus, the present application can claim the benefit of both of these earlier filed provisional applications.

The priority claims for prior filed provisional applications, which are governed by 35 U.S.C. 119(e), do not have the same requirements as priority claims to prior filed non-provisional applications, which are governed by 35 U.S.C. 120. There is NO requirement that a second-filed provisional application, e.g. Provisional '432, claim priority to or incorporate by reference a first-filed provisional application, e.g. Provisional '340. Indeed, a provisional application cannot claim priority to a previously-filed provisional application. A priority claim in a provisional application is "improper." As shown on page 3 of the attached appendix, MPEP 201.04(b) states "A provisional application is not entitled to claim priority benefits based on any other application under 35 U.S.C. 119. If applicant attempts to claim the benefit of an earlier U.S. or foreign application in a provisional application, the filing receipt will not reflect the improper >benefit or< priority claim". Moreover, a nonprovisional application that claims priority one or more prior filed provisional applications need not and "should not" specify its relationship with the prior provisional applications. (See MPEP 201.11 as shown on pages 1 and 2 of the attached Appendix.") With respect to the language of the priority claim in the nonprovisional application, all that is required is that the nonprovisional application provide the number and filing date of each prior provisional application on which the benefit claims are based. (See MPEP 201.11, which also appears on page 1 of the attached Appendix. "When the nonprovisional application is entitled to an earlier U.S. effective filing date of one or more provisional applications under 25 USC 119(e), a statement such as "This application claims the benefit of U.S. Provisional Application NO. 60/\_\_\_\_\_ filed, and U.S. Provisional Application No. 60\_\_\_\_\_, filed\_\_\_\_\_, should appear as the first sentence(s) of the description.").

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Thus, the present application properly claims the benefit of both Provisional '340 and Provisional '432, both of which antedate the publication date of Zhang, i.e., November 7, 2001.

With respect to the controls, amended claims 23, 29, 37, and 39 do not recite a control from the general population or a "select population" Claims 23, 29, 37, and 39 recite control subjects that are the same as the control subjects of claim 26.

With respect to the nature of the sample, the Examiner concurs that Provisional '340 teaches sub-populations of neutrophils and subpopulations of monocytes or combinations of these at page 9. (See page 9, line 4 of Provisional '340) Provisional '432 also teaches subpopulations of monocytes and neutrophils (See page 9, line 8, of Provisional '432.) Provisional '340 and Provisional '432 both teach blood as a sample. (See page 3 of Provisional '340 and '432.) In addition, Provisional '432 teaches serum, and plasma. (See page 2 of Provisional '432.). Since the present nonprovisional application is entitled to claim benefit to Provisional '340 and Provisional '432, both of which antedate Zhang, Applicants submit that §102/103 rejection based on Zhang and the nature of the sample is improper and request that it be withdrawn.

In view of the above-described amendments and remarks, applicants submit that, in addition to allowed claim 34, claims 1-5, 7-10, 23, 25, 26, 28, 29, 31-33, and 35-39 are now in conditions for allowance. Prompt notice of such allowance is respectfully requested. If the Examiner has any questions regarding the amendments or remarks, he is asked to call Pamela A. Docherty, at (216) 622-8416.

Respectfully submitted,

Date: 12/07/2006

By: Kristin J. Frost  
Kristin J. Frost, Reg. No. 50,627  
(216) 622-8895



## UNITED STATES PATENT AND TRADEMARK OFFICE

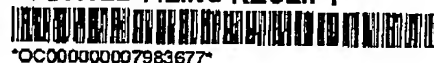
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WASHINGTON, D.C. 20231  
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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/039,753	01/02/2002	3736	579	26473/04177	11	22	6

24024  
CALFEE HALTER & GRISWOLD, LLP  
800 SUPERIOR AVENUE  
SUITE 1400  
CLEVELAND, OH 44114

CONFIRMATION NO. 9142

## UPDATED FILING RECEIPT



\*0C00000007983677\*

Date Mailed: 04/30/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Stanley Hazen, Pepper Pike, OH;  
Renliang Zhang, Cleveland, OH;

## Domestic Priority data as claimed by applicant

THIS APPLN CLAIMS BENEFIT OF 60/259,340 01/02/2001

AND CLAIMS BENEFIT OF 60/283,432 04/12/2001 \*

(\*)Data provided by applicant is not consistent with PTO records.

## Foreign Applications

If Required, Foreign Filing License Granted 02/14/2002

Projected Publication Date: 08/08/2002

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

## Title

Myeloperoxidase, a risk indicator for cardiovascular disease

RECEIVED  
DOCKETED

MAY 7 2002

T.L.B. IP. Dept.

Preliminary Class  
600

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Title 37, Code of Federal Regulations, 5.11 & 5.15**

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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	DRAWINGS	TOT CLAIMS	IND CLAIMS
60/259,340	01/02/2001		75	26473/04177	2		

24024  
CALFEE HALTER & GRISWOLD, LLP  
800 SUPERIOR AVENUE  
SUITE 1400  
CLEVELAND, OH 44114

## FILING RECEIPT

OC000000005812340

Date Mailed: 02/28/2001

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## Applicant(s)

Stanley Hazen, Pepper Pike, OH ;  
Renliang Zhang, Cleveland, OH ;

## Continuing Data as Claimed by Applicant

## Foreign Applications

If Required, Foreign Filing License Granted 02/28/2001

\*\* SMALL ENTITY \*\*

## Title

Methods of identifying subjects at increased risk for developing cardiovascular disease

## Preliminary Class

Data entry by : BUTLER, DAVINA

Team : OIPE

Date: 02/28/2001

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- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
- The title may be truncated if it consists of more than 600 characters (letters and spaces combined).
- The docket number allows a maximum of 25 characters.
- If your application was submitted under 37 CFR 1.10, your filing date should be the "date in" found on the Express Mail label. If there is a discrepancy, you should submit a request for a corrected Filing Receipt along with a copy of the Express Mail label showing the "date in."
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NO. 0337

P. 22

Page 3 of 3

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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FILE FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
60/283,432	04/12/2001		75	26473/04189	2		

24024  
CALFEE HALTER & GRISWOLD, LLP  
800 SUPERIOR AVENUE  
SUITE 1400  
CLEVELAND, OH 44114

CONFIRMATION NO. 4429

## FILING RECEIPT



\*OC00000006285424\*

Date Mailed: 07/06/2001

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## Applicant(s)

Stanley Hazen, Pepper Pike, OH;  
Renliang Zhang, Cleveland, OH;

If Required, Foreign Filing License Granted 07/05/2001

Projected Publication Date: N/A

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

## Title

Myeloperoxidase, a risk indicator for cardiovascular disease

RECEIVED

JUL 10 2001

C.J.L. I.P. DEPT.

Data entry by : ABRAHA, ZEWDITU

Team : OIPE

Date: 07/06/2001

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JUL 11 2001

T.L.B. m n

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Title 37, Code of Federal Regulations, 5.11 & 5.15**

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- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
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- The docket number allows a maximum of 25 characters.
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Appl. No. 10/039,753

Appendix to Amdt. Dated December 7, 2006

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## APPENDIX

### 37 CFR 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

(a)(4) A nonprovisional application, other than for a design patent, or an international application designating the United States of America may claim an invention disclosed in one or more prior-filed provisional applications. In order for an application to claim the benefit of one or more prior-filed provisional applications, each prior-filed provisional application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed provisional application must be entitled to a filing date as set forth in § 1.53(c), and the basic filing fee set forth in § 1.16(d) must be paid within the time period set forth in § 1.53(g). (Emphasis added.)

(5)

(i) Any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number).

### MPEP 201.11 \*\*>Claiming the< Benefit of an Earlier Filing Date >Under 35 U.S.C. 120 and 119(e)< [R-3]

\*\*\*

## III. REFERENCE TO PRIOR APPLICATION(S)

### B. Reference to Prior Provisional Applications

When the nonprovisional application is entitled to an earlier U.S. effective filing date of one or more provisional applications under 35 U.S.C. 119(e), a statement such as "This application claims the benefit of U.S. Provisional Application No. 60/---, filed ---, and U.S. Provisional Application No. 60/ ---, filed ---." should appear as the first sentence>(s)< of the description or in an application data sheet. In addition, for an application which is claiming the benefit under 35 U.S.C. 120 of a prior application, which in turn claims the benefit of a provisional application under 35 U.S.C. 119(e), a suitable reference would read, \*\*>"This application is a continuation of U.S. Application No. 10/---, filed ---, which claims the benefit of U.S. Provisional Application No. 60/---,

Appl. No. 10/039,753

Appendix to Amdt. Dated December 7, 2006

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filed —."<. In the case of design applications, it should appear as set forth in MPEP § 1504.20.

The relationship (i.e., continuation, divisional, or continuation-in-part) is not required and should not be specified when a prior provisional application is being claimed under 35 U.S.C. 119(e). No relationship should be specified because whenever a priority claim to a provisional application under 35 U.S.C. 119(e) is made, it is implicit that the relationship is "nonprovisional application of a provisional application." If a relationship between a prior provisional application and the nonprovisional application is submitted, it may be unclear whether the applicant wishes to claim the benefit of the filing date of the provisional application under 35 U.S.C. 119(e) or 120. Thus, applicants seeking to claim the priority to a provisional application under 35 U.S.C. 119(e) should not state that the application is a "continuation" of a provisional application or that the application claims 35 U.S.C. 120 benefit to a provisional application. Although 35 U.S.C. 120 does not preclude a benefit claim to a provisional application, it is not recommended that applicants claim the benefit to a provisional application under 35 U.S.C. 120 since such a claim could have the effect of reducing the patent term, as the term of a patent issuing from such an application may be measured from the filing date of the provisional application pursuant to 35 U.S.C. 154(a)(2). (emphasis added.)

### C. Benefit Claims to Multiple Prior Applications

A nonprovisional application that directly claims the benefit of a provisional application under 35 U.S.C. 119(e) must be filed within 12 months from the filing date of the provisional application.

### MPEP 201.04(b) Provisional Application [R-3]

### 35 U.S.C. 111 Application.

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#### (b) PROVISIONAL APPLICATION.-

(1) AUTHORIZATION.-A provisional application for patent shall be made or authorized to be made by the inventor, except as otherwise provided in this title, in writing to the Director. Such application shall include-

(A) a specification as prescribed by the first paragraph of section 112 of this title; and

(B) a drawing as prescribed by section 113 of this title.

(2) CLAIM.-A claim, as required by the second through fifth paragraphs of section 112, shall not be required in a provisional application.

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(3) **FEE.**-

(A) The application must be accompanied by the fee required by law.

(B) The fee may be submitted after the specification and any required drawing are submitted, within such period and under such conditions, including the payment of a surcharge, as may be prescribed by the Director.

(C) Upon failure to submit the fee within such prescribed period, the application shall be regarded as abandoned, unless it is shown to the satisfaction of the Director that the delay in submitting the fee was unavoidable or unintentional.

(4) **FILING DATE.**-The filing date of a provisional application shall be the date on which the specification and any required drawing are received in the Patent and Trademark Office.

(7) **NO RIGHT OF PRIORITY OR BENEFIT OF EARLIEST FILING DATE.**-A provisional application shall not be entitled to the right of priority of any other application under section 119 or 365(a) of this title or to the benefit of an earlier filing date in the United States under section 120, 121, or 365(c) of this title.

**MPEP 201.04(b)** further explains that:

A provisional application is not entitled to claim priority benefits based on any other application under 35 U.S.C. 119, 120, 121, or 365. If applicant attempts to claim the benefit of an earlier U.S. or foreign application in a provisional application, the filing receipt will not reflect the improper >benefit or< priority claim. Moreover, if a nonprovisional application claims the benefit of the filing date of a provisional application, and states that the provisional application relies upon the filing date of an earlier application, the claim for >benefit or< priority earlier than the filing date of the provisional application will be disregarded. (emphasis added.)